

Biopure Presentation by Thomas Moore, CEO

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Sapna Shirasava:

Good morning, and thank you for joining us. I'm Sapna Shirasava Biotechnology Analyst at ThinkEquity Partners and today it's my pleasure to introduce Tom Moore who is the CEO of Biopure. Biopure is one the companies we have closest relationship with and have followed for a long time. We are very excited about the company. It is the leader in [the field of Oxygen therapeutics. It is the first company which has filed a BLA with the FDA in the field of Oxygen therapeutics after over 40 years of work in that field and I'll let Tom tell us this very exciting story.

Thomas Moore:

Thank you very much, Sapna. Good morning everybody. Let's start off on a high note please with the, always popular, disclaimer. I'll give you a couple of seconds to look at that while I reattach my microphone. The unusual part about that disclaimer is that among other things, it says that anything we say here is not necessarily policy of the US Government. I'm told that Colin Powell now has to show a similar disclaimer before he makes his talks.

So, Biopure is a company that's devoted 19 years of its life to developing a totally new concept in therapeutics and pharmaceuticals. The first in class oxygen therapeutic. Our product for humans called, Hemopure, is a new class of pharmaceutical which is intravenously administered to deliver oxygen to tissues. While it was developed initially to provide an oxygen bridge for the immediate treatment of the signs and symptoms of acute surgical anemia, we're working on subsequent potential indications which include use in trauma, ischemia associated with surgery and other situations and in cancer treatment. In my talk this morning I will touch on how we are going to develop that, as well. Our product is a true biologic. It comes from biology. That is it comes from cows. In this case, red blood cells that we harvest from cows in sequestered herds we keep in Michigan. These red blood cells are then lodged open so that we can extract the hemoglobin within which is the core of our product. That hemoglobin is purified through a proprietary process which includes our own high-performance [lipid chromatography ?] process developed by our founder, Karl Rausch. This purified hemoglobin is then stabilized and [polymerized?] in order

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to form the ideal or what we believe is the ideal, particle size for safely distributing oxygen around the body. This polymer has an average weight in our human product of 250 kilo-Daltons, and in our veterinary product of 200 kilo-Daltons, and that is the only difference between the two products. This resulting product has many advantages versus red blood cells which we fondly refer to as RBCs.

First of all, because its pure hemoglobin, and because we have purified it to the point where it is stripped out of almost all other allergenic material, this product is compatible with all blood types. There's no tissue matching required to be administered to anybody. Second, it's a highly stable product and that is part of the choice in using bovine red blood cells to start this process. Our product has a shelf life of three years, and it's not three years under refrigeration or under special conditions, it's three years at room temperature or temperature as you would consider considerably above room temperature up to about 80-85 degrees Fahrenheit. Because it is a manufactured pharmaceutical that offers consistent potency and stability and purity, something which frankly, is hard to guarantee with red blood cells donated by human beings, and unlike human red blood cells, our product delivers oxygen immediately upon transfusion. Human red blood cells, once they have been stored for up to 5-8 days, begin to lose their immediate potency and distributing oxygen – it actually takes several hours for them to regain that potency in the human body. And so, for someone in need of added oxygen distribution in their body, our product is a real godsend. Finally, of course, we have an abundant and well controlled raw material source where as, as we'll talk about a little more later, human red blood cells are becoming increasingly scarce supply for any number of broad based reasons which we will touch on in just a minute.

So, that is what the product is. How does it work? Well, in the human body as you can see on this hemo on the left, under normal circumstances, red blood cells distribute oxygen throughout the body going through both the artery which you see is the larger tube on the left, and into the smaller arteries and capillaries which branch off to the right. When that situation happens, everything is doing great. However, when for reasons related to trauma or anemia, or surgery, the number of red blood cells get reduced, several things change. First of all, there are fewer red blood cells so there is obviously less oxygen being distributed as you can see in the center photo here. Secondly, the body automatically compensates for the reduced number of red blood cells by constricting arteries that serve various tissues in the body, in fact, ultimately, in the case of shock, basically shuts off all arteries except for those that serve the brain and the heart. The two most important organs. So, when Hemopure gets added to the body, other things begin to happen. Hemopure is represented by these orange dots that are flowing in the plasma around the red blood cells. First

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of all, as you can see in this schematic here, a great deal of more oxygen gets distributed thanks to the addition of Hemopure. In fact, Hemopure is two - three times more efficient at distributing oxygen around the body pound for pound than red blood cells and that stems from the fact that it is more aggressive about grabbing and giving up oxygen as it goes through the system. In fact, red blood cells only give out a third to a half of the oxygen that they're carrying in a pass through the body, while Hemopure gives out all the oxygen that's turning plus grabs some oxygen off the red blood cells and redistributes that as well. So, the addition of our product to the human body is very significantly and disproportionately increases the total oxygen getting distributed to the body. The second interesting thing that happens is because our product is one-one thousandth the size of a red blood cell, it really gets distributed to oxygen wherever the plasma itself gets distributed. In this case you can see the constricted artery to the right is where the Hemopure is able to penetrate and in fact distribute oxygen to places where the body itself is constricting the circulation of red blood cells. This has an important implication in other areas which we call ischemia where there is a blockage of red blood cells. That can happen as a by-product of cardiac surgery where debris coming from breaking up a clot can stop circulation temporarily in various parts of the heart or sometimes the brain. It also happens in situations more commonly called heart attack and stroke, where we believe our product ultimately could have some application, as well.

So, you've seen the product, you've seen a little bit about how it works. We ought to, I guess, eventually get around to talking about Biopure the company. From an investor prospective, I think we offer some very interesting opportunities. First of all, we are the leading developer of oxygen therapeutics. We have two products that have been developed and approved, a veterinary product and a human product. We offer a multi-billion dollar market opportunity which I will outline for you in just a minute. There is clearly a global need for a blood substitute based on supply shortages in developed countries and ongoing safety concerns in lesser developed countries and there are multiple applications for this product, a couple of which I just described to you before.

As a company, we are truly poised for commercialization. We own all the rights to our product, the technology and the patents. We have largest validated manufacturing capacity within this field of products. Lastly, we brought in new senior management over the past year which is leading the transition in this company from a research and development oriented firm to a true commercialization company. A word briefly about that. In the past year, and four months, we have brought in the five people you see highlighted in yellow here. Our strategy in all of this was to strengthen the company in three important areas: marketing, manufacturing and process capability and finally, finance, and we think we've done that. My background with 23 years with Proctor & Gamble,

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including running a world wide healthcare products business, as well as running Nelson Communications one of the largest pharmaceuticals sales and marketing services company [solidly ?] in the pharmaceutical marketing area as well as in general management. I joined the company a little over a year ago to shore up specifically in that area. Bob Richards has joined us as Chief Finance Officer. He's a San Francisco boy so he's sure happy to be back here. Many of you may know him from his work with Van Casper and other firms in investment banking, and he is shoring up our ability to work with the street and to chart our long-term financial future. Doug [Hansel ?] is our relatively new medical director. A experience in practicing clinical anesthetist. Barry Scott was vice president of international businesses [?] for Bristol Myers Squibb. He has joined us in a similar capacity. Donna Wolfe ran her own medical education company and is now running our long-term scientific exchange and medical education programs.

In addition, we shifted Karl Rausch, the founder of the company, to Chief Technology Officer; Frank Murphy who has done an excellent job as CFO to a new position as Senior Vice President of Engineering Process technology in both cases to improve focus in improving our manufacturing efficiency and making ready for the introduction of our new manufacturing facilities in the next couple of years which will expand both capacity but also our ability to manufacture those products at the lowest possible cost. Our board of directors is a distinguished one. Charles Sanders, Dr. Sanders, is first former chief executive officer of [Praxcel ?] as well as former president of Massachusetts General Hospital. Jim [Dittleson ?] is the co-founder of the company and previously a co-founder as well of Midwestern Corp. Dick Cloud is a former division chief of the FDA, extraordinarily insightful and a regulatory expert and C. Everett Coop is, what can I say, he's C. Everett Coop. But he's also spent four years on the development of blood substitutes, so he has a huge personal interest in this category.

So what about these products, a little more detail please. We have two products: Hemopure, which is our human product, which was approved for the treatment of acutely anemic surgery of patients in South Africa in 2001. As many of you know, we filed our biologic license application for treatment in acutely anemic orthopedic surgery patients with the FDA in the US in July 2002. They have since given us a complete review and has sent us some questions, and we will talk about where we stand on that process in just a moment. Oxyglobin is our veterinary product. It was approved for treatment in [anemia ?] dogs in 1998 in the US and 1999 in the European Union. We sold now, over 137,000 units. We recently introduced the new size to drive this business upwards. Both products have something important called the EDQM Certificate of Suitability. What that means is that we have passed the stringent requirements of the European regulatory authorities concerning our ability to remove all pathogens from our product and specifically the pathogens everybody thinks about when

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they think about cow blood, namely BFE. And we demonstrate that to the satisfaction of both the European Authorities, who are very picky about this one, as well as the FDA.

So where do we stand with our BLA at this point? As I mentioned, we submitted our BLA back in July of 2002, it was accepted in October of 2002. It was the first the BLA ever accepted by the FDA for a hemoglobin based oxygen carrier. The FDA in May indicated that it wanted to expand their action due date to the end of August and instead, they sent us a complete list of questions at the end of July. In the letter they sent us, they indicated the following:

First, they'd completed their review of our application. That there aren't going to be any more questions after the ones that they sent us, and that's a good thing, because they sent us a lot of questions. In fact, there are about 50 that are pretty substantial that are going to require a significant effort on our part to answer - and additional questions beyond that.

The agency has informally, since then, referred us to this letter as our road map and it is a road map we intend to follow and we are working very hard to get all these questions answered as quickly as possible.

After careful review of this letter in August, we decided we wanted to ask the agency for a meeting to both clarify the questions they asked and also to find, in a couple of cases, a mutually agreed upon range of data we are going to look at in order to give them their answers. Some of the questions are pretty broad reaching and we assumed that we would need a meeting in fact to get the answers to those questions. Since then, the agency has been extraordinarily responsive to our information requests. We have had six major contacts with them since we received the letter. Four in response to questions or correspondence sent to us. The turn out at these meetings have been unbelievable, frankly, in the four instances where we sent correspondence to the agency - in every case they responded in less than a day and in two cases, less than two hours. So, there is an extraordinarily close collaboration going on here, which is great. In that, we are getting the guidance that we expected we would have to have a meeting for back in August, considerably ahead of schedule. So, at this point, I'm not sure if a meeting is going to be necessary to round it off or not. At this point, there are just a couple of more questions to go through.

In the meantime, we're busy answering all the questions where we don't need any guidance, as well as reviewing the input we have had from the agency on some of these bigger questions in order to get our answer back ASAP. Everybody wants to know, when are you going to get your answer back? And, we want to be able to give you good guidance on that and we said we would get

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the meeting done in September and then we would know roughly where we stand. It's the middle of September so I think we have a week or two yet to sort of get our act together and take a look at what it's going to take to finish our response and after that is done, we will be able to provide some better guidance from that point. In the interim, we are busy answering questions as fast as we can.

What about the market opportunity? [While our initial indication process, file was for surgery ?]. Within that, because we are marketers now, we are focusing on the area that is going to be easiest to penetrate, and that is the area where people are practicing blood avoidance, and blood avoidance surgery. And the orthopedic surgery in the area in the US alone, has a potential market at about \$300,000,000. If you look at blood avoidance as practiced across the entire field of surgery in the US adds an additional \$450,000,000 market potential. We have applied some arbitrarily chosen and I think quite conservative penetration numbers to those markets to yield some early revenue projections for what we could do out of those indications. If we could move more broadly in the general surgery and get only 10% of general surgery use of blood at our planned marketing price of about \$700 per unit, that would add up to about a \$700,000,000 revenue opportunity. The three other areas we are working on are trauma, where we are working towards beginning trials later this year, this is for use in ambulances, secondly surgical ischemia where the product could be used in order to counteract the side effects that patients experience from the short-term ischemia as I mentioned early that were off on a by-product of surgery such as cardiac surgery and finally in the area of cancer therapy which is rather a counter intuitive indication for us, but basically there are a class of tumors called solid tumors, [in the ?] of the brain, mild small cell lung cancer, liver cancer, pancreas cancer and like, which are called solid tumors. These tumors are extraordinarily hard to kill and unfortunately, that's one reason why they are so extraordinarily lethal to patients, because in part, the way these tumors develop, there is a layer of tissue within these tumors which becomes [an-oxic ?], that is there is virtually no oxygen in that layer of tissue and because all of our treatment strategies for cancer, whether it is ionizing radiation or chemotherapy, depends on highly oxygenated active tissue to be effective, these tumors become extremely difficult to kill.

The application of our product in both animal testing and a very small phase I human trial, appears to have in fact sensitized these tumors to radiation, and offers the opportunity to be confirmed in the future human clinical trial to improve the kilo weight on these tumors per treatment, hopefully improve patient mortality as well. So those are the four key indication areas we are working on. The total potential, obviously, is huge. But we think it is realistically [able?] to be achieved by the company in years ahead.

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Use of this product in surgery. How urgent is that really? While there are many people who prefer not to get a blood transfusion from a stranger under any circumstances, there are also underlying demographic reasons, if you will, why this product would be important here. The rate of growth in our blood supply is now declining. It's declining for many reasons. First of all, as we place more and more restrictions on who's allowed to donate blood, the number of people who are eligible to do that is in fact declining. And secondly, the need for blood has gone up. As the baby boomers reach the ages of 55+, they are looking for new knees, new elbows, new hips, all of which are highly blood consumptive surgery. So, as the demand for blood over the past five years has been going 5%, the blood supply has only been going 3%. It is projected that demand is going to grow +7% pace, and that the supply of blood may actually drop to about flat. If you talk to physicians around the country today, they say, "well, for the last few years, we've seen shortages in January and in July, basically because people are on vacation and either on holiday or vacation, so they are not donating blood, but now shortages are almost constant." And unfortunately, that is projected to continue for sometime. So, we think there is a huge need for a good red blood cell substitute and that's one of the things this product can do. I mentioned early from a marketing standpoint initially, we are going to go after the target market of those who practice blood avoidance. Why? Because people have already made a commitment with time and effort and money to avoid getting red blood cells from a stranger. So, we can meet their need by giving them a pure pharmaceutical style product. The strategies they use are basically three fold. One is to pre-donate their own blood, called an Autologous donation, the second is to use a product called Erythropoeitin, which you've probably heard of, which stimulates red blood cells direction, both of which require office visits prior to surgery in order to set it up, two office visits to pre-donate two units of blood for Autologous and four office visits to receive four shots for EPO. Unfortunately, this is a highly wasteful approach. Half of the pre-donated blood or half of the Erythropoeitin use for orthopedic surgery is in fact not needed. Because half of orthopedic surgery patients don't end up needing a transfusion. So, all of this effort is in fact, well, at least 50% wasted. The other sad fact is that of those who do need the transfusion, half of them require more than two units, so at least in the case of those who pre-donated two units, they end up getting blood from a stranger, anyway. So if you look at pre-autologous donation as part of this market, 75% of time, it actually doesn't succeed in its principal objective.

Here's a financial spread of how that might look from an economic standpoint of our product. In this chart, each one of these cases is two patients each and basically was pre-autologous donation. The cost of two units each for two patients is \$350.00 leading to a \$1,400 total cost, in the case of in-hospital transfusion, there's an extra fee of \$200, which comes to a total cost of \$1,600 for two patients, or \$800 per patient. Erythropoeitin at \$400 a shot is twice as

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expensive. Hemopure, given to only one of the two patients who actually ends up needing blood comes in at about the same as pre-autologous donation, but significantly cheaper than EPO. Of course, cheaper also in terms of the time and effort and risk associated with it as well. So we think we have a good [?]. Our clinical experience with this product was quite extensive, over 200 clinical trials, pre-clinical studies, 22 human clinical trials, and a great deal of experience in both the veterinary and human market in general. This is an overview of the number of trials we've done and the people involved. Basically, it totals 806 people taken Hemopure under highly controlled clinical circumstances.

The efficacy standard the FDA set for our product was that we needed to demonstrate 35% replacement of red blood cells with our product. That is, 35% of patients who took our product did not need to switch to red blood cells at any time. And we significantly exceeded that in both our phase III trial in general surgery and orthopedic surgery at 43% and 59%. In fact, within that, if you look at the trial over time, in the first week, 70% of patients in our clinical trial, avoided taking red blood cells, only because by protocol, they are not allowed to get Hemopure after day 7, but the number ultimately dropped as low as 59%. From a safety standpoint, our agreement with FDA was that the primary safety endpoint would be based on a peak analysis which was a separate analysis of the data done by an independent and blinded medical panel. That panel concluded that our product was not inferior to red blood cells in respect to overall medical risk. This is not the only way the agency looks at safety but it is the primary safety endpoint.

We have very strong intellectual property. A great deal of patents. I'm going to give you eye strain for at least half a second. There they all are. But, if you just look at the date line on the right hand side, you'll see how the vast majority don't expire until 2014, or later. And frankly, most of the intellectual property in the more recent ones get carried over to the later patents. Currently, we have a 75,000 facility unit in Cambridge, Massachusetts, which we are expanding to 100,000 units within the next year. We are working on financing for a 500,000 unit Sumter facility in Sumter South Carolina, which would obviously vastly increase our capacity, drive down unit cost, and basically would be the pivotal advance we need to do in order to get this company to profitability.

From a competitive standpoint, Hemosol is now on a clinical hold. It is not clear whether it will be able to resume. Northfield has developed a product strictly for trauma use, they are hoping to begin enrollment in their clinical trial for Phase III by the end of the year. Their product is vastly different in its storage and shelf life and characteristics. We think our product represents a more attractive and option for use in trauma because of it's ability to be stored at room temperature rather than in refrigeration, and the market will tell us. Our strategy

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from here is to prepare for the US launch in orthopedic surgery. We are developing a strategy in using a highly experienced medical device, an orthopedic medical device, sales force to do the principal selling job against our surgeon primary client, and then create medical science liaison teams who will train the balance of hospital staff so they'll know how to use our product both safely and effectively. Otherwise, we are going to roll revenues by building our South Africa sales. We are negotiating strategic alliances designed to allow our product to be introduced into other geographic areas and we're taking initiative to expand our veterinary business, most recently with the introduction of a new smaller bag size, which is also more profitable for us.

Clinically, we are working on getting the approval and the introduction to begin our orthopedic indication. We aim to begin our trauma studies later this year. Ischemia later this year as well. Cancer will be our 2004 project. We have worked hard to keep our balance sheet strong. Point in fact, our cash on hand has steadily improved in the past year and has correlated nicely with the status of our stock price.

That's our story. I appreciate your attention and I will begin your break out across the hall in the Nob Hill room. I look forward to talking with many of you there. Thank you very much.